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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/526,582	03/16/2000	Judith Fitzpatrick	SRX 110	1732

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EXAMINER	
COUNTS, GARY W	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 10/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/526,582	FITZPATRICK ET AL.	
	Examiner	Art Unit	
	Gary W. Counts	1641	

--The MAILING DATE of this communication appears on the cover sheet with the correspond nce address --

THE REPLY FILED 02 September 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires __months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on *02 September 2003*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *see attached*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: *NONE*.

   Claim(s) objected to: *NONE*.

   Claim(s) rejected: *1-22*.

   Claim(s) withdrawn from consideration: *NONE*.

8. ☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

BAO-THUY L. NGUYEN
PRIMARY EXAMINER

Gary W. Counts
Examiner
Art Unit: 1641

DETAILED ACTION

Continuation of 5 NOTE: Applicant argues that the Oberhardt patent does not disclose the correlation between apolipoprotein levels in saliva and blood. This is not found persuasive because Examiner has not relied upon the Oberhardt patents for the correlation in saliva to blood but rather has relied upon Schneider (US 6,291,178) for this teaching. Applicant further argues that neither Oberhardt patent provides description of saliva collection, removal of mucopolysaccharides or reason to remove mucopolysaccharides. This is not found persuasive because Examiner has not relied upon the Oberhardt patents for the collection of saliva and removal of mucopolysacchardies but rather has relied upon the Fellman reference for teaching the advantages of collection of saliva and removal of mucopolysaccharides.

Applicant argues that the Fellman reference does not disclose detecting apolipoproteins in saliva with antibodies, or that the levels can be correlated with levels in serum. This is not found persuasive because Examiner has relied upon Oberhardt for the teaching of detecting apoliporoteins in saliva with antibodies and has relied upon Schneider et al for teaching the correlation of proteins in saliva with that in serum.

Applicant argues that Kundu does not teach why or how the levels of apolipoproteins should be detected in saliva, nor how to correlate the levels of the apolipoproteins in saliva with the levels of the apolipoproteins in the serum. This is not found persuasive because Kundu discloses detecting apolipoprotein A in a saliva sample by imunoreacting labeled monoclonal antibodies with the Apo A in the sample, specifically against kringle 5 domain of apo A (col. 4, lines 39-52, and column 8, lines 8-15). With

respect to how to correlate the levels of the apoliporoteins in the saliva with the levels of the apolipoproteins in serum, Schnieder et al teaches the correlation of a saliva sample with a blood sample to determine an amount of analyte of interest and specifically teaches that the correlative equivalence of analyte values in saliva in relation to blood levels provides the advantage of utilizing non-invasive procedure in determining analyte concentration in a patient by collecting saliva rather than drawing blood from the patient.

Applicant argues that Schneider (US 6,291,178) has a filing date only of August 30, 1999 and is therefore not available as prior art. This is not found persuasive because Schneider (US 6,291,178) claims priority to U.S.S.N 08/978,729, filed on November 26, 1997, now Pat. No 5,968,746 and the Examiner has relied Schneider ('178 and '746)for teaching that is in known in the art to correlate a saliva sample with a blood sample to determine an amount of analyte of interest and because Schneider was combined with Oberhardt and Fellman only for reasons that saliva analyte have a correlation with serum analyte. Therefore, Oberhardt (US 6,291,178) is available as prior art.

Applicant further argues that Schneider is a qualitative, not a quantitative assay to detect hydrophilic compounds and Schneider provides for extensive dilution of sample – which may alter the amount of apolipoprotein measured in a given volume, thereby completely destroying one's ability to correlate the levels of apolipoprotein measured in the sample with the levels measured in the serum. Once again this is not found persuasive because Examiner has not relied upon Schneider for the reasons stated above but rather has relied upon Schneider for the teaching that it is known in the art to correlate a saliva sample with a blood sample to determine an amount of analyte of

interest. Applicant further argues that Schneider discloses that hydrophilic compounds can be detected in saliva and mentions hydrophilic proteins (col 2, line 41) and states that apolipoprotein is not a hydrophilic protein. This is not found persuasive because it is not commensurate to the issues because Examiner has relied upon Schneider for teaching that it is known in the art to correlate a saliva sample with a blood sample to determine an amount of analyte of interest and one skilled in the art would recognize that you would not have to collect a sample by invasive procedures to determine an analyte of interest.

Applicant argues that Fisher and Coppo do not suggest detecting apoplipoprotein in saliva, nor that the levels could be correlated with the levels in the serum by measuring the values of the albumin. This is not found persuasive because Examiner has not relied upon Fisher and Coppo for these limitations. Examiner has relied upon Fisher and Coppo for normalizing the amount of apolipoprotein to the amount of albumin present in the saliva sample and antibodies immunoreactive to albumin in the device or kit for determining apolipoprotein concentration.

BAO-THUY L. NGUYEN
PRIMARY EXAMINER
9/30/03